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U.S. Patent No. 5,356,810 which issued on 18 October 1994 is assigned on its face to Gist-Brocades N.V. and claims benefit to U.S. Serial No. 424,376 filed 12 November 1989.

Therefore, U.S. Patent No. 5,356,810 is not an effective reference as to the instant application. Moreover, the issued patent and the instant application are assigned to different owners.

The doctrine of obviousness-type double patenting is one which developed through the case law. For example, as stated in In re Van Ornum & Stang (214 USPQ 761 (CCPA 1982), copy attached hereto)

"...application claims were directed to mere obvious modification of, or improvements on, inventions defined in the claims of patents already issued **to the same inventors, or to common assignees...**" [Emphasis ours] (page 10 of the attached copy)

Clearly neither of those conditions exist, the inventive entities of the relied on patent and of the instant application are different, and the relied on patent and the instant application are assigned to different entities. Thus it is not possible to lodge an obviousness-type double patenting rejection in the instant application over the Fleno et al. patent.

More recently as taught in In re Berg, 46 USPQ 2nd 1226 (Fed. Cir. 1989), copy attached hereto,

"Obviousness-type double patenting...requires rejection of an application claim when the claimed subject matter

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is not patentably distinct from the subject matter claimed in a **commonly owned patent**. [Emphasis ours] Its purpose is to prevent an unjustified extension of the term of the right to exclude granted by a patent by allowing a second patent claiming an obvious variant of the same invention to issue **to the same owner later**. [Emphasis ours] (page 5 of the attached copy)

Again, as noted hereinabove, the instant application and the patent relied on are not owned by the same entity and thus common ownership does not exist. In both the Fleno et al. patent and the instant application, the inventors thereof assigned their rights to Gist-Brocades and to Igene, respectively, the real parties in interest. Hence, it is impossible to lodge an obviousness-type double patenting rejection because common ownership does not exist.

Another phenomenon associated with the instant application is that the patent relied on by the Examiner has an effective filing date subsequent to the priority date of the instant application. Thus, if examination of the instant application and of the Fleno et al. application had occurred in order of the filing dates, the instant application would have issued prior to the Fleno et al. patent and the instant rejection would not have been possible.

But for the rate of progress of examination in the Patent Office associated with the instant application could the aberrant rejections of the instant application occur.

However, the rate of progress of prosecution in the instant

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application is a matter over which the instant applicants have no control and thus the instant applicants should not be penalized by the rate of progress of the various applications as they mature in the Patent Office.

"...applicants...should not be penalized by the rate of progress of the applications through the PTO, a matter over which the applicants does not have complete control." (In re Braat, 19 USPQ 2d 1289, Fed. Cir. 1991) (paragraph bridging pages 6 and 7 of the copy attached hereto)

In fact, on 16 December 1993, nearly a year before the issuance of the Fleno et al. patent, applicants had submitted a responsive Amendment and a copy of a Rule 132 Declaration¹ demonstrating the reproducibility, and hence enablement, of the instant application.

However, apparently, that Declaration was never considered at that time.

Accordingly, there is no legal basis for maintaining the obviousness-type double patenting rejection because the very reason for having such a rejection, namely, the unjustified extension of

¹ As noted in the facsimile confirmation attached hereto, 20 pages were transmitted to the Patent Office. The Amendment comprised 15 pages including the Amendment per se, a copy of the Rule 132 Declaration and a copy of a deposit receipt. A Petition for Extension of Time was filed in duplicate for a total of four pages. The facsimile cover sheet was the 20th page transmitted to the Patent Office.

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monopoly to an owner, does not exist as to the instant application. Moreover, the rate of progress of the applications in the Patent Office cannot be overlooked by the Examiner. Fleno et al. cannot be used to penalize the instant applicants. Therefore, applicants believe that the rejection is improper and must be removed.

In item 19 at the bottom of page 3 of the Office Action, claims 25-34 remain rejected under 35 U.S.C. §112, first paragraph. Essentially, the Examiner requested that additional deposits be made to enable the instant invention or that product-by-process claims be introduced, which would be allowable.

The rejection is traversed for the following reasons.

Applicants have maintained that the instant application is enabled fully and that deposits are not required because the instant application teaches a fully reproducible method for making a mutant yeast which falls within the scope of the claims of the instant application.

In support thereof, applicants filed a Declaration Under 37 C.F.R. §1.132 which provided data on the development of numerous strains which fall within the scope of the instant claims. For example, Experiment 1 provided **seven** independently derived strains with enhanced astaxanthin content. Experiment 2 provided **nineteen** different, newly developed strains with enhanced astaxanthin

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content. Experiment 3 revealed **eleven** new strains with enhanced astaxanthin content. Experiment 4 provided **sixty-five** individual, newly developed strains of mutant yeast producing great amounts of astaxanthin which fall within the scope of the instant claims. Experiment 5 provided **twenty-two** additional independent strains having enhanced astaxanthin content.

Thus, applicants have provided evidence of the reproducibility of the instant invention. More than 100 newly developed strains of yeast with enhanced astaxanthin content within the scope of the instant claims have been produced by practicing the teachings of the instant application and that evidence is set forth in the Declaration of record.

Clearly, deposits are not required because an artisan on practicing the teachings of the instant invention would be able to obtain without undue experimentation other examples of mutant yeast producing enhanced levels of astaxanthin. It is believed applicants have more than amply demonstrated the reproducibility of the instant application.

Accordingly, a prima facie case of non-enablement has not been made. Instead, the application is in full compliance with the Patent Statute. Hence, withdrawal of the rejection is in order.

In item 20 on page 5 of the Office Action, the Examiner also rejected claims 25-34 under 35 U.S.C. §112, first paragraph for

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want of enablement. The Examiner was concerned with the breadth of the claims.

The rejection is traversed for the following reasons.

In re Colianni (195 USPQ 150, CCPA, 1977), copy attached hereto, sets forth the requirements for demonstrating enablement.

For example, one of the factors in determining what constitutes undue experimentation is the quantity of any necessary experimentation.

As demonstrated in the instant specification and in the Rule 132 Declaration of record, all of the teachings required to practice the instant invention are set forth in the instant application. Thus, there is no great degree of necessary experimentation required to practice the instant invention. Clearly the amount of experimentation required of the artisan to practice the instant invention is not undue and is instead routine because the instant application provides all of the necessary direction and guidance to practice the instant invention.

Another factor to be considered is the presence of working examples.

The instant application provides a reproducible method for making yeast with enhanced astaxanthin content and provides working examples to that effect. Moreover, applicants provided by way of the above-discussed Rule 132 Declaration, abundant evidence of

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reproducibility of practicing the instant invention, more than 100 additional strains of yeast falling within the scope of the claimed invention were made practicing the teachings of the instant application.

Ex parte Forman et al., 230 USPQ 546 (BOPAI 1986), copy attached hereto, teaches that the factors for determining what is undue experimentation include the amount of direction or guidance presented.

The evidence of record demonstrates that the teachings of the instant specification are sufficient to practice the full scope of the invention as claimed.

Other factors are the nature of the invention, the state of the prior art and the relative skill of the artisan.

The instant invention relates to, in general, and is practiced in the context of mutagenizing and selecting microorganisms in culture. Those are techniques well known and practiced in the industry. Because microbes are tested for individual mutants, a tremendous number of organisms can be screened in a very short period of time, well within the parameters of what would be considered routine experimentation. Moreover, the evidence of record demonstrates that practicing the methods of the instant application, an artisan will obtain yeast within the scope of the instant invention.

The evidence of record demonstrates the reproducibility of the

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instant invention thereby satisfying yet another of the Forman criteria.

Hence, Applicants believe there is no basis to conclude that the instant invention is not enabled. There is no basis to conclude that the instant application does not provide sufficient guidance and direction to an artisan such that the artisan on practicing the teachings set forth in the instant specification would not obtain a yeast as claimed. In the absence of any specific evidence of non-enablement, it is believed the §112, first paragraph rejection must be removed.

The Examiner relied on *In re Fisher* to support his position of alleged non-enablement and excessive breadth of the claims. However, the facts of the *Fisher* case and the amount of evidence in support of claim scope provided in *Fisher* pales in comparison to that of record in the instant application. In *Fisher*, there was evidence of only a doubling of biologic activity in an art where any increase of activity was long sought and where the product was a pharmaceutical for use as a drug in humans.

On the other hand, the instant invention relates to mutagenizing and selecting microorganisms in culture. Those are techniques well known and practiced in the industry. A tremendous number of organisms can be screened in a very short period of time, well within the parameters of what would be considered routine experimentation. Moreover, the evidence of record demonstrates

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that practicing the methods of the instant invention, an artisan will obtain yeast within the scope of the instant invention. Applicants provided evidence of producing over a hundred additional strains with enhanced astaxanthin content.

The Examiner also relied on the Fiers case. That was a case which related to a DNA and focused on the concept of simultaneous conception and reduction to practice of a nucleic acid molecule. The passage relied on by the Examiner derived from a discussion of a party who disclosed a method for isolating a fragment of a DNA and a method for isolating an mRNA but did not disclose a complete DNA as required in the count.

The party argued that language in the specification that the corresponding cDNA could be obtained by practicing certain methods satisfied the Patent Statute. However, the fact remains that the count related to a specific DNA and the party did not have that nucleic acid in his possession when the application was filed. Therefore, the application provided no more than a plan for obtaining the DNA.

It is notable that the arguments relate more to satisfaction of the written description requirement rather than enablement requirement. Clearly, as to the current law of claiming nucleic acids, without a description of the nucleic acid, one cannot have conceived of same and thus an application would fail to provide a written description of the claimed nucleic acid.

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On that basis, then, the Fiers case is irrelevant to the instant application as Fiers relates to written description of a nucleic acid and not necessarily to enablement of mutant yeast. Fiers did not have the DNA. On the other hand, applicants had numerous strains of yeast with enhanced astaxanthin content in their possession at the time the parental applications were filed. Fiers did not provide sufficient guidance to make such a DNA. The instant application teaches thoroughly, as proved by the evidence of record, how to obtain a yeast within the scope of the invention as claimed.

In any event, the instant application teaches a reproducible method for obtaining a mutant yeast with enhanced astaxanthin content. The claimed invention is clearly described as to the patentable features of interest and clearly was in the possession of applicants at the time the instant application and the benefit cases relied on were filed.

Moreover, the instant application does not relate to any pigments as asserted by the Examiner but to astaxanthin. In support of the claim for same, applicants have demonstrated that by practicing the instant invention, an artisan will routinely and without resort to undue experimentation obtain yeast with enhanced astaxanthin content, as claimed, within the scope of the claimed invention.

Therefore, any allegation of unpredictability has been

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dispelled by the evidence of record. The instant specification and the evidence of record prove the reproducible nature of the invention. Clearly, the evidence of record is commensurate in scope with the invention as claimed.

In view thereof, a prima facie case of non-enablement has not been made. Moreover, evidence of enablement of the claimed invention is of record. Hence, withdrawal of the rejection is in order.

In item 21 at the bottom of page 6 of the Office Action, claims 25-34 remain rejected under 35 U.S.C. §102(e) or §103(a) over U.S. Patent No. 5,356,810.

The rejection is improper because U.S. Patent No. 5,356,810 is not an effective §102(e) reference to the instant invention. U.S. Patent No. 5,356,810 has an effective filing date of 12 November 1989 which is subsequent to the 8 August 1988 filing date of parental application U.S. Serial No. 229,536. Hence, the rejection is improper, the cited patent is not an effective reference against the claims of the instant invention and thus the rejection must be removed.

CONCLUSION

Applicants have had to endure an inordinate delay in the examination of the instant application. The Declaration Under 37 C.F.R. §1.132 was filed on 16 December 1993 but only considered within the past year.

Moreover, the obviousness-type double patenting rejection is improper because U.S. Patent No. 5,356,810 has an effective filing date subsequent to the effective filing date of the instant application and is not commonly owned with the instant application. Clearly the obviousness-type double patenting rejection is improper and the Fleno et al. patent, U.S. Patent No. 5,356,810 is not an effective reference against the claims of the instant application.

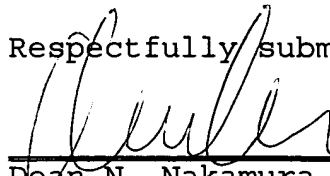
Finally, there is ample evidence to support the conclusion that the specification and claims are enabled fully. In view thereof, Applicants respectfully urge that the rejections be removed and the instant application be passed to allowance.

The undue burden to the Assignee should be terminated. However if the Examiner maintains the improper rejections, Applicants will be forced to appeal the rejections which are believed to be wholly improper and without foundation. Accordingly, due deliberation, thorough consideration of the evidence of record and early indication of allowance are requested respectfully.

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Applicants hereby petition for any extension of time which may be required to maintain pendency of the instant application. Any fees for such extension are to be charged to Deposit Account No. 19-4880.

Respectfully submitted,



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